

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF OHIO

EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE

LITIGATION

This document relates to:

See cases listed in Exhibit A

MDL 2804

Case No. 17-md-2804

Hon. Dan Aaron Polster

**OMNIBUS MOTION FOR LEAVE TO AMEND TO ADD AUROLIFE DEFENDANTS
AND MEMORANDUM OF LAW IN SUPPORT**

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INTRODUCTION

In accordance with this Court's Order dated May 23, 2024, Doc. #5455, the Plaintiffs listed in Exhibit A ("Amending Plaintiffs") hereby move for leave to amend their operative complaints pursuant to Federal Rules of Civil Procedure 15 and 16 to add the Aurolife Defendants¹ beyond the deadline for amendment of pleadings set forth in this Court's case management orders, and submit this Omnibus Memorandum of Law in support thereof. If permitted to amend, Plaintiffs here would supplement their existing pleadings with claims substantially similar to those asserted against manufacturers in the first amended CT4 bellwether complaint in *City and County of San Francisco et al. v. Purdue Pharma, LP, et al*, No. 3:18-cv-07591-CRB, Doc. #128 (Mar. 21, 2020) (adjusted for the law of their particular jurisdiction), and additional defendant specific facts, including those detailed herein. None of the Amending Plaintiffs have sued Aurolife in their currently operative pleadings.

Leave should be granted because, as more fully described below, the most recent ARCOS data obtained from the federal Drug Enforcement Administration (DEA) shows that in the period 2014-2019, Aurolife had a market share of 5% or more in each of the Amending Plaintiff's jurisdictions. This data did not become available to the Amending Plaintiffs until September 12, 2023, well after the deadline for plaintiffs to amend their pleadings under the applicable case management orders in this MDL. During the earlier period for which ARCOS data had been made available, 2006-2014, Aurolife had

¹ The Aurolife Defendants are Aurolife Pharma LLC and Aurobindo Pharma USA, Inc. (together, "Aurolife").

less than a 5% market share in each of the Amending Plaintiffs' jurisdictions. Thus, even with the exercise of due diligence, the Amending Plaintiffs could not have met the deadline for adding Aurolife because the information on which they are basing their claims did not exist at that time.

Because they could not, even with due diligence, have met the deadline to amend their complaints to add claims against Aurolife, and because, as discussed below, Aurolife will not be prejudiced by these amendments, this Court should find that each of the Amending Plaintiffs has shown "good cause" within the meaning of Rule 16, that amendment is proper under Rule 15, and should grant their motions to amend their pleadings to add Aurolife.

FACTUAL BACKGROUND

The facts pertaining generally to the procedural history of these cases and the deadlines set by the Court for the amendment of pleadings are set forth in the PEC's Roadmap Overview for Motions for Leave to Amend, which Amending Plaintiffs incorporate by reference herein and to which the Court is respectfully referred.

Facts Pertaining to Aurolife

Aurolife is a manufacturer of generic prescription opioids. It was an opportunistic seller of hydrocodone and oxycodone – entering those markets in 2012 and 2013 as sales peaked overall and other manufacturers began limiting their sales in response to the opioid crisis. As others limited their market participation, Aurolife increased its own.

Aurolife first began selling generic hydrocodone in 2012. From 2012 to 2019,

Aurolife sold nearly 900 million DUs of hydrocodone – 94% of which were sold between 2015 and 2019. Its market share with respect to hydrocodone peaked in 2019 at 5.73% on sales of over 231 million DUs.

In 2013, shortly after entering the hydrocodone market, Aurolife began selling generic oxycodone, which became its best-selling opioid. Between 2013 and 2019, Aurolife sold over 1.1 billion DUs of oxycodone – 90% of which were sold between 2015 and 2019. Its oxycodone market share peaked in 2017 and 2018, at 5.56% and 5.21%, respectively.

Aurolife began selling generic codeine in 2014. From 2014 to 2019, it sold over 288 million DUs of codeine – 98% of which were sold between 2015 and 2019. Aurolife began capturing a substantial 11% share of the national codeine market in 2017, on sales of nearly 65 million DUs. Its sales steadily increased in 2018 and 2019, with nearly 83 million and 91 million DUs sold, respectively. Its national codeine market share correspondingly increased from 16.7% to its peak of 21.4% during those years.

In 2016, Aurolife began selling generic versions of methadone, hydromorphone, and oxymorphone. During the period between 2016 and 2019 Aurolife sold:

- over 120 million DUs of methadone, with its share of the national market peaking at 11.04% during this period;
- over 34 million DUs of hydromorphone, with its share of the national market peaking at 5.86% during this period; and
- over 8.5 million DUs of oxymorphone, with its share of the national market peaking at 9.68% during this period.²

² Details pertaining to Aurolife's market share in each Amending Plaintiff's jurisdiction are set forth in Exhibit A.

The Current Motion

On May 24, 2024, this Court granted the PEC's motion to lift the moratorium on motion practice to allow non-bellwether MDL plaintiffs to seek leave to amend their pleadings in order to add defendants they had not previously named. Doc. 5455. The Amending Plaintiffs – none of whom previously sued Aurolife – now seek leave to amend to add claims against Aurolife based on the updated ARCOS data. Each Amending Plaintiff is a jurisdiction in which: (1) Aurolife did not have a 5% or greater market share with respect to prescription opioids during three of the nine years (2006-2014) covered by the original ARCOS data; and (2) the updated ARCOS data showed that Aurolife had a 5% or greater market share with respect to prescription opioids during the period 2015-2019.³ The jurisdiction-specific facts pertaining to each Amending Plaintiff's jurisdiction claims are shown on Exhibit A. The Amending Plaintiffs seek to assert the same claims against Aurolife that they asserted against the same category of defendants – manufacturers/labelers – in their currently operative complaints.

As described below, none of the Amending Plaintiffs could have met the applicable deadline for amendment with respect to Aurolife because the information on

³ The updated ARCOS data made available to the PEC, like the original data the DEA produced in this litigation, pertains to 14 opioid drugs: buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, powdered opium, oxycodone, oxymorphone, and Tapentadol. The market share calculations are based on either dosage units ("DU") or the total morphine milligram equivalent ("MME"). Data is at the county-level.

which they seek to base their claims was not available at that time, or indeed at any time prior to September 12, 2023. As further discussed below, amendment of these cases to include Aurolife will not prejudice those defendants because the Amending Plaintiffs' actions have all been stayed.

LEGAL STANDARD

The legal standards applicable to this motion are set forth in the PEC's Roadmap Overview for Motions for Leave to Amend, which Amending Plaintiffs incorporate by reference herein and to which the Court is respectfully referred.

ARGUMENT

I. THE AMENDING PLAINTIFFS HAVE "GOOD CAUSE" TO AMEND THE SCHEDULING ORDER TO ADD THE AUROLIFE ENTITIES AS DEFENDANTS

A. Despite Their Diligence, the Amending Plaintiffs Could Not Meet the Original Deadline with Respect to Aurolife

The Amending Plaintiffs readily meet the diligence test for amending the scheduling order to permit amended pleadings: the information on which they seek to base their amended pleadings was not available until September 2023, more than four years after the deadline for amendments had passed. *See Rapp v. Forest City Techs., Inc.*, No. 1:20-cv-2059, 2021 WL 4713394, at *3-4 (N.D. Ohio June 17, 2021) ("Because this evidence was not reasonably available to Rapp until well after the deadline date passed, Rapp could not reasonably have met the deadline despite due diligence."); *Fijalkowski v. Belmont Cnty. Bd. of Comm'rs*, No. 2:17-cv-195, 2018 WL 1835444, at *2 (S.D. Ohio Apr. 18, 2018) ("New information can constitute good cause under Rule 16(b)."); *Joseph v. Joseph*, No. 1:16-cv-465, 2017 WL 5953119, at *2 (S.D. Ohio Jan. 10, 2017) (finding good cause

existed when “the documents upon which the proposed amendment [was] largely based were not produced until more than two months after the . . . motion to amend deadline.”). This was so because the updated ARCOS data, which demonstrated the significant market share of Aurolife from 2015 to 2019 in each of the Amending Plaintiff’s jurisdictions, was not available before then.

Despite Amending Plaintiffs’ due diligence, it was impossible for them to identify and name Aurolife based on the previously available ARCOS data (2006-2014). As of March 16, 2019, the deadline for amending pleadings under the scheduling order, the Amending Plaintiffs were provided only with the identity of entities with *more* than 5% market share in their jurisdictions; the PEC was precluded from providing plaintiffs with information about entities with less than 5% market share in their jurisdictions. See Doc. #1106. Aurolife did not meet that threshold in the Amending Plaintiffs’ jurisdictions for the 2006-2014 ARCOS data period and thus were not identified to these plaintiffs as potential defendants.⁴ The more recent information provided in the updated ARCOS data was not available to these plaintiffs prior to the expiration of the amendment deadline and provides “good cause” for each Amending Plaintiff to amend its complaint to add Aurolife. See *Salerno v. Fam. Heritage Life Ins. Co. of Am.*, No. 1:23-

⁴ By the time the ARCOS data became generally publicly available, the March 16, 2019 deadline for amendment had passed. But it made no difference: even now, Amending Plaintiffs have chosen to name only those entities with at least a 5% market share in their jurisdictions. Aurolife did not have that market share in the Amending Plaintiffs’ jurisdictions during the 2006-2014 period. Thus, even when the ARCOS data became publicly available, the Amending Plaintiffs had no basis to sue Aurolife. Only the DEA’s production of updated ARCOS data alerted them to the fact that Aurolife had increased its market share during the period 2015-2019.

cv-01419, 2024 WL 2235772, at *2 (N.D. Ohio May 17, 2024) (“Sixth Circuit courts regularly grant leave for a party to amend its pleadings when discovery “apparently confirmed [the party’s] suspicions so that the company could assert [additional] claims.”); *see also Rapp*, 2021 WL 4713394, at *3–4; *Fijalkowski*, 2018 WL 1835444, at *2; *Joseph*, 2017 WL 5953119, at *2.

B. Aurolife Will Suffer No Undue Prejudice If Plaintiffs Are Permitted to Amend

It is clear that Aurolife will suffer no prejudice from the filing of the amended complaints at issue here. That is because each of the Amending Plaintiffs’ cases has been stayed since the original deadline for the filing of amended pleadings. There has been no discovery, no motion practice, no litigation of any kind. Aurolife will be in the exact same position, with respect to each of Plaintiffs’ cases, that it would have been in had the cases been stayed with Aurolife already in them. *See Phelps v. McClellan*, 30 F.3d 658, 663 (6th Cir. 1994) (among the factors considered in assessing prejudice from a delayed amended pleading are “whether the assertion of the new claim or defense would . . . require the opponent to expend significant additional resources to conduct discovery and prepare for trial [or] significantly delay the resolution of the dispute . . .”). *Cf. Duggins v. Steak 'N Shake, Inc.*, 195 F.3d 828, 834 (6th Cir. 1999) (where discovery and dispositive motion deadlines had passed, and a motion for summary judgment had been filed, amendment to add a different claim would create significant prejudice to defendants); *Fraker v. Marysville Exempted Vill. Sch.*, 696 F. Supp. 2d 887, 893 (S.D. Ohio 2010) (plaintiff could not amend to add new defendants after

close of discovery and briefing of motion for summary judgment; new defendants would be “severely prejudiced if they were added at this late juncture, having been deprived of their right to conduct discovery and file dispositive motions”).⁵

This is especially true because Aurolife has known since early in this MDL that they were defendants in some cases before this Court. In that circumstance, the need to defend additional cases does not constitute undue prejudice. *See In re Nat’l Prescription Opiate Litig.*, No. 21-4051, 2022 WL 20701236 (6th Cir. Nov. 10, 2022) (litigation costs of being named in additional cases not undue prejudice because defendants knew that they could face these costs from the time they were added to the MDL). Nor could Aurolife rely on the relatively small number of cases in this MDL in which they were named to estimate the likely scope of their liability. That is so because the statute of limitations has not run on claims against them.⁶ Aurolife has always known that

⁵ Cf. *In re Nat’l Prescription Opiate Litig.*, 956 F.3d 838 (6th Cir. 2020) (precluding amendment of scheduling order where defendants had been subject to discovery and briefing on substantive motions, and where plaintiffs had previously disavowed claims they later sought to add).

⁶ In most instances, the Amending Plaintiffs’ primary claim is for abatement of public nuisance, and the underlying nuisance of the opioid epidemic is an ongoing condition in which, with respect to most jurisdictions, no statute of limitations applies. *See, e.g., In re Nat’l Prescription Opiate Litig.*, 589 F.Supp.3d 790, 826 (N.D. Ohio 2022) (“absolute and statutory public nuisance claims are exempt from a statute of limitations”) (applying Ohio law); *see also In re Nat’l Prescription Opiate Litig.*, No. 1:17-CV-02804, 2019 WL 2477416, at *4 (N.D. Ohio Apr. 1, 2019), report and recommendation adopted in part, 2019 WL 3737023 (N.D. Ohio June 13, 2019) (same, applying Montana law); *City of Huntington v. AmerisourceBergen Drug Corp.*, 609 F.Supp.3d 408, 471 (S. D. W. Va. 2022) (“until the harm is abated, the public nuisance is continuing and the statute of limitations does not accrue”) (applying West Virginia law); *In re Opioid Litigation*, No. 400000/2017, 2018 WL 3115102, at *12 (N.Y. Sup. Ct. June 18, 2018) (“The rule with respect to nuisance or other continuing wrong is that the action accrues anew on each day of the wrong, so that the right to maintain the cause of action continues as long as

governmental entities – whether plaintiffs in this MDL or not – could file new cases against them.

Indeed, if leave to amend is not granted, the Amending Plaintiffs can simply file their claims against Aurolife in new stand-alone cases. Thus, the question is not *whether* the new claims against Aurolife will be brought; the question is *where* these claims will be brought. The issue, then, is whether these claims arising from the same opioid crisis are coordinated for discovery and management with other claims against the same defendants and/or the same category of defendants. In this context, Rule 1’s command that the Federal Rules be construed and administered to secure the “just, speedy, and inexpensive determination of every action and proceeding” counsels in favor of permitting the addition of Aurolife. Fed. R. Civ. P. 1. In any event, Aurolife cannot demonstrate that they will be prejudiced by having the claims against them coordinated in these proceedings rather than scattered around the country. *See* 28 U.S.C. § 1407 (actions may be transferred and coordinated upon determination such transfer “will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions.”); *In re Nat’l Prescription Opiate Litig.*, MDL No. 2804, Transfer Order at 3 (J.P.M.L. Dec. 5, 2017) (finding that centralization and coordination of opioid cases “will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation.”).

Because the Amending Plaintiffs have shown both diligence and lack of

the nuisance exits”) (applying New York law).

prejudice, this Court should find “good cause” under Rule 16 to amend the scheduling order to permit the filing of amending pleadings against Aurolife.

II. AMENDMENT OF THE PLEADINGS IS PROPER UNDER RULE 15

The requirements of Rule 15 are also satisfied. Under Rule 15, “the court should freely give leave [to amend] when justice so requires.” Fed. R. Civ. P. 15(a)(2). Because the Rule 16 standard is recognized to be more “stringent,” see *Landstar Ranger, Inc. v. City of Delaware, Ohio*, No. 2:22-CV-02008, 2022 WL 7322274, at *4 (S.D. Ohio Oct. 13, 2022), and to set a “higher threshold,” *J&R Passmore, LLC v. Rice Drilling D, LLC*, No. 2:18-CV-1587, 2024 WL 111661, at *1 (S.D. Ohio Jan. 10, 2024) (quoting *Shane v. Bunzl Distrib. USA, Inc.*, 275 F. App’x 535, 536 (6th Cir. 2008)), a party that can establish diligence and lack of prejudice under Rule 16 can generally satisfy the broader, more liberal standard of Rule 15. In this case, leave to amend should be granted in the interests of justice.

Only two of the Rule 15 factors—bad faith and futility of amendment—are not subsumed within the Rule 16 “good cause” analysis. See *Brumbalough v. Camelot Care Ctrs., Inc.*, 427 F.3d 996, 1001 (6th Cir. 2005) (identifying “undue delay in filing, lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and futility of amendment” as factors to be considered under Rule 15).⁷ Neither is

⁷ A finding of sufficient diligence will satisfy the requirement that there was no undue delay; lack of notice and undue prejudice both fall within the prejudice analysis of Rule 16. Finally, repeated failures to cure deficiencies would presumably negate good cause, but in any event is entirely inapplicable here, as the Amending Plaintiffs have not

applicable here. As noted above, the Amending Plaintiffs seek to add claims against Aurolife similar to those they have asserted against other manufacturers – and similar to claims this Court previously found sufficiently stated to preclude dismissal under Rule 12. Nor is there, nor could there be, any suggestion of bad faith with respect to any of the Amending Plaintiffs. Because the Amending Plaintiffs have shown good cause under Rule 16 and because it is in the interest of justice to permit them to amend their pleadings in order to add Aurolife, the requirements of Rule 15 are also satisfied.

CONCLUSION

For the foregoing, reasons, this Court should grant leave to all of the Amending Plaintiffs to amend their complaints in order to add Aurolife.

Dated: July 29, 2024

Respectfully submitted,

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previously attempted to cure deficiencies, nor have any deficiencies in their pleadings been identified.

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CERTIFICATE OF SERVICE

I hereby certify that on July 29, 2024, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF system.

/s/ Peter H. Weinberger
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